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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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22852	7590	08/01/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			BOESEN, AGNIESZKA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,816	Applicant(s) HOVANESSION ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 18, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,17-25 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,12-16,26,28 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>See Office Action</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received May 18, 2006.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-9, 13-16, 26, 28, and 32 is acknowledged. Applicant's argument has been fully considered and is persuasive. Applicants argue that SEQ ID NO: 1 is a consensus motif present in all strains of HIV-1 and HIV-2 and request that SEQ ID NOS: 2, 4, and 5 be examined along with SEQ ID NO: 1. The examiner also rejoined claim 12, because claim 12 is drawn to a vaccine as in claims 13-16. Thus claims 1-9, 12-16, 26, 28, and 32, SEQ ID NOS: 2, 4, and 5 are examined on the merits. Claim 12 is

Claims 10-12, 17-25, and 29-31 are withdrawn because the claims are drawn to the non-elected invention. Claims 1-9, 13-16, 26, 28, and 32 are under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Information Disclosure Statement received January 27, 2005 and August 11, 2005 have been considered and the copies are attached to this Office Action.

Art Unit: 1648

The following reference WO 02/05587 is in a foreign language accompanied by the claims in English. Due to this, the reference has been examined only to the extent of the disclosure in the claims.

Claim Objections

Claim 26 is objected to because of the following informalities: The claim recites “the method according to Claim 26”. Appropriate correction is required.

Claims 5, 6, 8, and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims should refer to other claims in the alternative only and cannot depend from other multiple dependent claims. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected because of use of the trademark Gerbu®. The trademark should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Art Unit: 1648

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 12-16, 26, 28, and 32 are rejected under 35 U.S.C. 112, first paragraph,

as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a pharmaceutical composition, wherein the peptide in the composition comprises variants of the peptide sequences SEQ ID NOs: 1 to 9. The variants of the peptide sequences comprise amino acid additions, deletions and/or substitutions in SEQ ID NOs: 1 to 9. The specification does not provide examples of the claimed variants of peptide sequences SEQ ID NOs: 1 to 9. The applicant has not shown that peptides, which have been varied by amino acid additions, deletions and/or substitutions are capable of inducing monoclonal, polyclonal or oligoclonal antibodies with restricted specificity to SEQ ID NOs: 1 to 9, as it is disclosed. The claims are also drawn to the pharmaceutical composition comprising the said peptides, wherein at least one peptide has 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The specification describes that the peptides having 90% to 99.9999% sequence homology of the peptides of SEQ ID NOs. 1 to 9, included in the compositions, are the instantly claimed variants [0128]. The specification contemplates production of a genus of peptides that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The instant specification provides insufficient description of all peptides that have 90% to 99.9999% homology to SEQ ID NOs 1-9.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is a partial structure in the form of a recitation of percent homology. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making peptides that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The particular peptides are required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The immunogenic potential of isolated peptides and their ability to induce peptide specific antibodies depends on the numerous factors including the presence or absence of

Art Unit: 1648

particular amino acid residues within the candidate immunogenic peptide. The instant specification describes generation of antibodies with restricted specificity against peptides of SEQ ID NOs 1-9. The generated antibodies will subsequently bind and neutralize the caveolin binding motif within the gp41 protein of the HIV virus. In order for peptide-specific antibodies to recognize a protein containing the same sequence found in the peptide, the amino acids in the protein must be accessible to the antibody. Thus, protein sequences need to be analyzed to ascertain that they meet the following criteria: (1) the stretch of the protein sequence to which the antibody will bind needs to be exposed to the solvent; and, (2) the sequence must be composed of amino acids without structures unrecognizable for the antibody, and the amino acids in the exposed sequence need to be hydrophilic containing polar or charged residues, particularly Arg and Lys (Tam. Synthetic peptide vaccine design: Synthesis and properties of a high-density multiple antigenic peptide system. 1988, PNAS, Vol. 85, p. 5409-5413). Changes in amino acid residues such as amino acid additions, deletions and/or substitutions can drastically affect the antigenic specificity of the peptides. Goldstein et al., (Two B cell epitopes of HIV-1 tat protein have limited antigenic polymorphism in geographically diverse HIV-1 strains, Vaccine, 2001, Vol. 19, p.1738-1746). demonstrated that truncation of amino terminal amino acids in Tat protein of HIV virus resulted in declining titers of Tat specific antibodies generated by immunization of rabbits with the modified peptides.

In view of these teachings indicating that modifications of amino acid residues in the peptides designed to induce neutralizing antibody responses, can cause loss of the antigenic specificity, and because of the limited examples in the specification of variant peptides that retain the requisite activity, there is insufficient written description support to demonstrate

Art Unit: 1648

possession of complete genus comprising peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9.

Claims 1-9, 12-16, 26, 28, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the sequences set out in SEQ ID NOs: 1 to 9, does not reasonably provide enablement for variants of the said sequences that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Wands factors are as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Changes in the amino acid sequence of the antigen can have a direct effect on the ability of the antibody to bind the protein, furthermore, the changes that effect the antibody binding do not have to occur within the epitope binding region (Abaza et al. Effects of amino acid substitutions outside an antigenic site on protein binding to monoclonal antibodies of predetermined specificity obtained by peptide immunization. Journal of Protein Chemistry (1992) Vol. 11, No. 5, pages 445-454). A single point mutation in HIV alters the structure of the polypeptide to such a an extent that neutralizing antibody will no longer recognize the sequence (di Marzo et al. Loss of a neutralizing epitope by a spontaneous point mutation in the V3 loop of

Art Unit: 1648

HIV-1 isolated from an infected laboratory worker. Journal of Biological Chemistry 1993, Vol. 268, No. 34, p. 25894-25901).

The current specification provides sufficient guidance for one skilled in the art to make a pharmaceutical composition comprising peptides represented in SEQ ID NO: 1 to 9. However, the specification does not provide sufficient guidance and/or factual evidence for one skilled in the art to make and/or use peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The claimed invention is directed to a pharmaceutical composition comprising peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The peptide variant that immunologically reacts with antibodies raised against a CBD-1 peptide or a CBD-2 peptide does not provide sufficient guidance for which amino acids in the claimed sequences may be changed/deleted or substituted for while the peptide will still react with CBD-1 or a CBD-2 peptide and thus have the capability to induce the antibodies with desired specificity.

The scope of the invention is very broad, encompassing a large number of peptide sequences that may or may not react with antibodies raised against a CBD-1 or a CBD-2 peptide.

It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the molecule in many instances. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over polypeptides of related function upon a significant amount of further research. See the following publications that support this unpredictability (Baker et al., Protein

Art Unit: 1648

structure predication and structural gemonics. Science (2001) Vol. 294, No. 5540, pages 93- 96;
Attwood, T. The babel of bioinformatics. Science (2000) Vol. 290, no. 5491, pages 471-473].

As stated above, the teachings in the current specification are not commensurate in scope with the claims because the breadth of the claims embrace a large number of possible sequences that differ from the peptide sequences set forth in SEQ ID NO: 2 to 9. In conclusion, the current specification and the claims coupled with the art of record at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable making and using peptide sequences of SEQ ID NO: 2 to 9 but the specification and the claims do not reasonably provide enablement for an immunogenic composition comprising peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9.

One would have to engage in undue experimentation in order to practice the claimed invention based on the Wands Factors including the lack of guidance in the application's disclosure, the unpredictability of producing peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9 and immunologically react with antibodies raised against CBD-1 or a CBD-2 peptide.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The prediction cannot be made from the disclosure how to make peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9 and immunologically react with antibodies raised against CBD-1 or a CBD-2 peptide. Therefore, in view of the speculative nature of the invention, the lack of predictability of the prior art, the

Art Unit: 1648

breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Claims 1-9, 12-16, 26, 28, and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant invention is drawn to a pharmaceutical composition and a vaccine composition comprising peptides of SEQ ID NOs 1-9 and peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOs 1-9. The specification does not sufficiently support the claimed vaccines. The term “vaccine” by definition implies any preparation intended for active immunological prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products. Although just about any protein when inoculated can cause an immune reaction, the prophylactic nature of this reaction is not guaranteed and has to be experimentally determined. Prophylaxis is defined as the prevention of disease or of a process that can lead to disease. This is achieved by use of an antigenic (immunogenic) agent to actively stimulate the immunological mechanism, or the administration of chemicals or drugs to members of a community to reduce the number of carriers of a disease and to prevent others contracting the disease. The specification describes the elicitation of an immunoglobulin response in mice to peptides that are identified as caveolin binding domain of the gp41 protein of the HIV peptide. There is insufficient evidence that such a study would correlate with *in vivo* efficacy in humans.

The successes as well as failures of various approaches in the field of HIV vaccine development have been summarized by McMichael and Hanke, HIV vaccines 1983-2003. Nature Medicine 2003, Vol. 9, p.875-880. Pazner (Identifying epitopes of HIV-1 that induce protective antibodies, Nature Immunology 2004, Vol. 4, p.199-210) discusses the obstacles to the development of an effective HIV-1 vaccine using epitope peptides to induce protective antibodies.

The currently available HIV envelope immunogens and immunization methodologies and protocols, are ineffective in eliciting potent and long lasting cross-reactive neutralizing antibody responses, which are required for protection from viruses such as HIV that express envelope glycoproteins that are heterologous to the immunogens. The immunization with HIV-1 envelope protein gp140 did not protect the macaques from the heterologous simian-human immunodeficiency virus infection (Xu et al., Immunization with HIV-1 SF162-derived Envelope gp140 proteins does not protect macaques from heterologous simian-human immunodeficiency virus SHIV89.6P infection. Virology, 2006, Vol. 349, p.276-289.)

It has been also observed that antibodies against the envelope protein of HIV-2 that do cross react with those against HIV-1 instead of providing protection, increase the susceptibility to HIV-1. Based on the epidemiological data HIV-2 infection does not protect against HIV-1 and is not suitable as a model for HIV-1 vaccine development (Greenberg AE. Possible protective effect of HIV-2 against incident HIV-1 infection: review of available epidemiological and in vitro data. AIDS (2001) Vol. 15, No. 17, pages 2319-2321.)

Although, animal models are an essential resource for evaluating the safety and comparative immunogenicity of candidate AIDS vaccine strategies, the animal models cannot

Art Unit: 1648

determine whether a vaccine will be effective against HIV-1 infection of humans. The assurance of vaccine effectiveness can only be established in Phase II trials (Feinberg et al. Aids Vaccine Models : challenging challenge viruses. Nature Medicine, 2002, Vol. 8, pages 207-210).

Due to the large quantity of experimentation necessary to generate the vaccine recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification in light of the high degree of unpredictability in the art regarding which structural features are required in order to provide protection, the absence of working examples directed to same, the complex nature of the invention, an undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of 35 U.S.C. 102(b) which forms the basis for all rejections under this section made in this office action set forth in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Berman et al., (US Patent 6,042,836, herein Berman).

The claims are drawn to a pharmaceutical composition and a vaccine comprising peptides of SEQ ID NO: 1 to 9 and variants thereof, wherein the peptides immunologically react with antibodies raised against a CBD-1 or CBD-2 peptide. The composition further comprises an adjuvant.

Art Unit: 1648

The specification discloses that "CBD-1 peptide" refers to a caveolin-binding domain peptide corresponding to amino acids 619 to 633 in HIV-1, the numbering being according to the consensus amino acid sequence of the gp41 ectodomain.

Berman discloses vaccine composition that contains HIV proteins such as gp41 (see column 12, lines 25-29) comprising an adjuvant (column 12 lines 5-20). HIV gp41 is expected to have the motif of SEQ ID NO: 1. While it is noted that the reference does not teach the specific peptides derived from gp41 protein, the use of the claimed peptides as immunogens will result in generation of the same antibodies that can be generated using the whole protein gp41 encompassing the claimed peptides. The antibodies generated due to immunization of an animal with the whole gp41 protein will immunologically react with the caveolin-binding domain peptide of HIV-1. Thus by this disclosure Berman anticipates the subject matter of the current claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 12-16, and 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al., (Immunology Letters, 2001, herein Dong) in view of Rubinstein et al., (US Patent 6,447,778, herein Rubinstein).

Art Unit: 1648

Claims are drawn to a pharmaceutical composition comprising at least one peptide of SEQ ID NO: 1, which is WXXXXWXXW, where W is tryptophan or an aromatic amino acid and X is any amino acid that is not aromatic, and a pharmaceutically acceptable carrier. The composition is presented in a multimeric or polyvalent manner and it is also encapsulated with a polymer. The claims are also drawn to an adjuvant such as for example aluminum hydroxide. The current specification teaches that SEQ ID NO: 1 represents a caveolin-binding motif of gp41 protein and spans amino acid residues 623-631.

Dong teaches SEQ ID NO: 1, a tryptophan rich motif with tryptophan residues at amino acid positions 623, 628, and 631 within the C domain of the gp41 protein of HIV virus (see Fig 1a, page 218 left column, and page 218). Dong teaches the importance of the said motif in Envelope-mediated fusion and that tryptophan residues in the said motif are extremely high conservative (see page 218). Dong also teaches that N- and C-domains of the gp41 protein may be used in an epitope-vaccine to induce neutralizing antibodies that may have protective activity against HIV fusion with the target cell (see page 219). The person of skill in the art would have been motivated to use peptides, which are known to possess conserved residues, for immunization purposes, because the antibodies with the specificity for the said peptides would recognize the caveolin-binding motif in the gp41 protein across different viral strains.

Dong does not teach a pharmaceutically acceptable carrier, an adjuvant, the composition which is multimeric or polyvalent, or encapsulated with a polymer. Rubinstein teaches a pharmaceutical composition comprising a peptide derived from gp41 protein of HIV, a pharmaceutically acceptable carrier (see the entire document, particularly column 10, lines 1-8), an adjuvant such as Freund's and aluminum hydroxide adjuvant (see column 49, lines 55-59), a

Art Unit: 1648

multimeric and polyvalent presentation of peptides in the composition (see abstract and Example XIV), and microencapsulation of peptides in the composition using polymers (see column 3, lines 35-41).

It would have been obvious to the person of the ordinary skill in the art to provide a pharmaceutical composition comprising peptide motif of SEQ ID NO: 1, arranged in a polyvalent manner and encapsulated with a polymer, in a pharmaceutically acceptable carrier, and an adjuvant. The person of ordinary skill in the art would have been motivated to formulate Dong's vaccine containing peptide motif of SEQ ID NO: 1 in Rubinstein's pharmaceutically acceptable carrier, and an adjuvant, wherein the peptides are arranged in a polyvalent manner and encapsulated with a polymer because Rubinstein suggests to use a pharmaceutically acceptable carrier such as an adjuvant, a polyvalent vaccine, as well polymer microencapsulation, in his vaccine composition comprising peptides derived from gp41 of HIV. The person of ordinary skill in the art would have had a reasonable expectation of success to provide a pharmaceutical composition comprising Dong's peptide motif formulated according to Rubinstein's teachings, and to induce the desired immune responses using the said composition, because such compositions have been routinely prepared and used in the art. Therefore the current claims are obvious over Dong's vaccine and peptide motif formulated in Rubinstein's pharmaceutical composition.

Art Unit: 1648

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035.

The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

7/21/06

Stacy B. Chen 7/24/06
STACY B. CHEN
PRIMARY EXAMINER